Association for Accessible Medicines

Your Generics & Biosimilars Industry

March 2, 2020

Dear Chairman Lesser, Chairman Scanlon, and all the distinguished members of the Insurance and Real Estate Committee.

The Association for Accessible Medicines (AAM) is the leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines.

The Association for Accessible Medicines (AAM) respectfully <u>opposes</u> the portions of Raised Bill 5366 ("RB 5366") relating to patent settlements and importation. These provisions will not help lower drug prices and present serious legal concerns.

AAM recognizes the need to address prescription drug prices and supports efforts to suppress truly anticompetitive behavior. As drafted, RB 5366 does not accomplish either of those important goals. Instead, it impairs private contracts and seeks to impose price controls on sales of patented prescription drugs. Such price control provisions are preempted by federal patent law and raise significant additional constitutional concerns.

RB 5366 is also a solution in search of a problem—there is already a robust federal framework in place under *FTC v. Actavis* to carefully review and police patent settlements that delay competition beyond the periods contemplated by Congress. And that framework has worked—as the FTC has conceded, "'[t]he data are clear: the Supreme Court's *Actavis* decision has significantly reduced the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers.'"[1] By creating a disparate state framework, RB 5366 raises the serious prospect that generic entry will be delayed and that legal consequences will vary dramatically across state lines. RB 5366 also raises dormant commerce clause concerns by seeking to regulate wholly extraterritorial pricing decisions and agreements.

AAM is also concerned that RB 5366's provision to allow commercial-scale importation of Canadian drugs under Section 804 Importation Programs ("SIPs") is unauthorized, unworkable, and will <u>not</u> result in significant cost savings to American patients. On the contrary, it likely will expose Connecticut citizens to increased safety risks from adulterated, counterfeit, and substandard drugs. Moreover, by impairing generic drug competition in the U.S., it likely will have the perverse effect of increasing prescription drug costs to Connecticut patients.

For all these reasons, AAM respectfully **<u>opposes</u>** the portions of RB 5366 relating to patent settlements and importation in their current form. Below, AAM briefly details particularly concerning provisions and aspects of RB 5366.

I. PROVISIONS RELATING TO PATENT SETTLEMENTS

[1] Federal Trade Commission, "FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors," May 23, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent.

A. RB 5366 Is Preempted By Federal Patent Law

As a threshold matter, RB 5366 improperly seeks to impose mandatory price controls on the sales of patented prescription drugs. Indeed, RB 5366 expressly requires that the Insurance Department automatically impose a 50% wholesale price reduction for brand name drugs subject to patent settlement agreements that purportedly "delay" competition.[2]

Courts have repeatedly recognized that these exact types of state price controls for patented prescription drugs are preempted by federal patented law. For example, in *BIO & PhRMA v. District of Columbia*, the Federal Circuit found that nearly identical provisions seeking to "restrain excessive [drug] prices" were preempted by patent law because they "stood as an obstacle to the federal patent law's balance of objectives as established by Congress."[3] As in *PhRMA*, RB 5366 imposes mandatory price reductions on the sales of patented drugs. It is therefore invalid and preempted.

B. RB 5366 Violates the Dormant Commerce Clause

RB 5366 also raises significant constitutionality concerns because it seeks to directly regulate pricing decisions that occur wholly outside of Connecticut. Under the dormant commerce clause, "a state may not adopt legislation that has the practical effect of establishing 'a scale of prices for use in other states.'"[4]

RB 5366 establishes precisely such an invalid price scale. Indeed, it directly regulates price decisions that take place almost exclusively outside the state—it imposes mandatory price reductions for ***all*** prescription drugs subject to settlement agreements and impairs a variety of contracts that may be entered outside of Connecticut. The Constitution does not tolerate such naked efforts by one of "the several States" to regulate interstate commerce.

C. RB 5366 Impairs a Broad Range of Private Contracts

RB 5366 is unconstitutional for the additional reason that it negates a broad range of private contracts. "No state shall . . . pass any . . . Law impairing the obligation of Contracts."[5] To determine whether a state law "passes the constitutional line," the Supreme Court applies a two-step test.[6] First, the Court assesses whether the state law "has 'operated as a substantial impairment of a contractual relationship.'"[7] Second, the Court examines the means and ends of the legislation and whether the state law is drawn in a "reasonable" manner.[8]

RB 5366 fails both of these tests. It impairs a wide range of contracts—not limited to settlement agreements—between pharmaceutical companies by seeking to negate the benefit of those contracts. It also substantially penalizes both branded and generic companies for entering into those agreements by imposing mandatory and immediate price reductions. Such punitive legislation is not necessary to achieve the stated "ends" of reducing drug prices. RB 5366 is therefore invalid.

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[2] RB 5366, § 3.

[3] *BIO and PhRMA v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

[4] *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989).

[5] U.S. Const., Art. I, §10, cl. 1.

[6] *Sveen v. Melin*, 138 S. Ct. 1815, 1821-22 (2018).

[7] *Id.*

[8] *Id.*

D. RB 5366 is Inconsistent with *FTC v. Actavis*

RB 5366 is also problematic because it is fundamentally inconsistent with *FTC v. Actavis*.[9] In *Actavis*, the Supreme Court expressly rejected the precise type of presumptive ban on pharmaceutical patent settlements that RB 5366 seeks to impose.[10] Instead, the Supreme Court held that the rule of reason—an antitrust test that has been in place for 100+ years—should be used to carefully review and assess pharmaceutical patent settlements and weigh their benefits and effects.

Without explanation, RB 5366 seeks to depart from and effectively overrule *Actavis*. To date, AAM has seen no evidence or analysis that would justify such a radical overhaul of the law, especially where *Actavis* has indisputably worked. As the FTC itself has recognized, "[r]everse-payment agreements using side deals and no-AG commitments [have] decline[d] to [their] lowest level in 15 years."[11] Given that *Actavis* is indisputably working to eliminate alleged "pay for delay," there is simply no need for a sea change in the law.

Nor is there any need for states such as Connecticut to inject themselves into patent settlement agreements. Indeed, there is already a robust federal framework in place that obviates the need for any state legislation. By statute, the FTC reviews Hatch-Waxman and BPCIA settlement agreements and initiates proceedings when necessary. The FTC also has a broad array of enforcement tools to deter and appropriately penalize anticompetitive behavior. Connecticut has not provided any justification for creating a distinct, fundamentally inconsistent state regime when the existing federal framework is more than sufficient.

E. RB 5366 Penalizes Procompetitive Settlement Agreements

RB 5366 is also premised on the incorrect proposition that Hatch-Waxman and BPCIA settlements are inherently anticompetitive. In fact, Hatch-Waxman and BPCIA patent settlements are typically ***procompetitive*** and enable generic entry prior to patent expiration. These settlements have taken years—if not decades—off the patent term for numerous drugs, including blockbusters. For example, Humira® biosimilars will enter the market approximately ***11 years*** before expiration of the latest of the 136 Humira® patents owned by AbbVie.

These procompetitive, pro-consumer benefits are confirmed by numerous other studies. For example, a study by the IMS Institute for Healthcare Informatics found that settlement led to generic drugs being introduced, on average, ***81 months*** (6.75 years) prior to patent expiry.[12] Similarly, one generic company estimated in 2009 that its settlements had "removed 138 years of monopoly protection" and provided $128 billion in savings to consumers through early generic entry.[13]

Importantly, these procompetitive results—entry long before patent expiration—may not be achieved by continued litigation. Indeed, brand companies ***frequently prevail*** in patent litigation. In fact, one study estimates

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[9] 570 U.S. 136 (2013).

[10] *Id.* at 158-59.

[11] Federal Trade Commission, "FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors," May 23, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent.

[12] *See, e.g.*, https://www.patentdocs.org/2013/07/ims-study-shows-pro-competitive-effects-of-reverse-payment-settlement-agreements-in-anda-litigation.html.

[13] *See* Teva Pharms. USA, Press Release, Teva Pharmaceuticals Issues Statement in Response to Federal Trade Commission Claims on Patent Settlements (June 24, 2009).

that generic companies lose patent litigation ***greater than 70% of the time*** at trial.[14] By incentivizing companies to litigate to finality—rather than settle—RB 5366 will very likely produce more outcomes where generic/biosimilar companies are ***off the market through patent expiration***. Thus, RB 5366 may further delay—and will certainly not expedite—generic entry.

F. RB 5366 Chills Settlement and Increases Litigation Costs

Because RB 5366 imposes mandatory and punitive price reductions, both branded and generic/biosimilar companies will be disincentivized to settle if there is any risk that their settlement could be deemed anticompetitive. Instead, those companies will litigate to (potentially unsuccessful) finality—or simply not bring patent challenges at all.

Litigation to finality will lead to dramatically higher costs. Indeed, the Federal Circuit has found that "[t]he costs of patent litigation are enormous with an average patent case costing upwards of ***$3 million*** for each side."[15] And "[o]ne study found that the cost of litigation in this specific context—a generic challenging a brand name pharmaceutical patent—was about ***$10 million per suit***."[16] These costs are borne by the entire health care system.

Removing settlement as a viable tool also disincentivizes patent challenges generally. As Chief Justice Roberts explained in his *Actavis* dissent, "[t]aking the prospect of settlements off the table—or limiting settlements to an earlier entry date for the generic, which may still be many years in the future—puts a damper on the generic's expected value going into litigation, and decreases its incentive to sue in the first place."[17] If patents are challenged less frequently, early generic entry will occur more infrequently.

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II. PROVISIONS RELATING TO IMPORTATION

RB 5366 also raises serious safety and drug pricing concerns by seeking to create a Section 804 Importation Program ("SIP") in Connecticut that could be approved by FDA if and when its proposed rule to allow importation of certain prescription drugs from Canada is finalized.[18] AAM is concerned that FDA's proposed rule—and thus the Connecticut SIP created by RB 5366—cannot be implemented in a manner that protects American patients from additional safety risks from counterfeit, adulterated, and substandard medicines or results in a significant reduction in the cost of covered prescription drugs. To the contrary, AAM is concerned that FDA's proposed rule and RB 5366, if enacted, will impair generic drug competition in the U.S. in a manner that results in increased prescription drug costs.

First, AAM is concerned that the proposed rule and individual SIPs like the one proposed in RB 5366 will further weaken the incentives for the development of safe and effective generic drugs at a time when the generic drug industry is especially fragile and subject to increasing financial and competitive pressures. For example, the

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[14] *See, e.g.*, Lex-Machina, Hatch-Waxman / ANDA Litigation Report 2017, available at https://www.globalpatentgroup.com/wp-content/uploads/2017/11/LexMachina-2017-HatchWaxman-Report.pdf; Gregory Glass, Legal Defenses and Outcomes in Paragraph IV Patent Litigation, 10 J. Generic Meds. 4, 8 (2013).

[15] *Ohio Willow Wood Co. v. Thermo-Ply, Inc.,* 629 F.3d 1374, 1376–77 (Fed. Cir. 2011) (Moore, J., concurring).

[16] *Actavis*, 570 U.S. at 170 (2013) (Roberts, C.J., dissenting) (citing Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795, n. 41 (2011)).

[17] *Actavis*, 570 U.S. at 176.

[18] *See* 84 Fed. Reg. 70796 (Dec. 23, 2019).

proposals appear to permit the importation of Canadian drugs before any generic drug could be approved in the U.S. and without the need to invest in costly litigation to overcome blocking patents. In addition, the proposals appear to permit importation prior to and during a "first applicant's" 180-day exclusivity period, significantly undermining the value of this incentive intended to spur early generic competition. If the proposed rule and RB 5366 impair generic drug competition in the U.S., it could have the perverse effect of actually *increasing* prescription drug costs for American patients.

Second, there is no evidence that importation under the proposed SIP will pose no additional risk to the public's health and safety. To the contrary, by creating cracks in America's closed distribution system, FDA's (and Connecticut's) proposed importation scheme will entail unavoidable additional risks to the health and safety of American patients from counterfeit, adulterated, and substandard prescription drugs. Neither FDA nor the State of Connecticut have the resources to effectively monitor the safety and integrity of drugs imported from Canada, including by conducting inspections of foreign manufacturers, foreign sellers, importers, and qualified laboratories. And the Canadian health authorities are unlikely to pick up the slack. AAM is concerned that these gaps in regulatory oversight will open up a significant hole in the otherwise closed American distribution system that is likely to be exploited by counterfeiters or other foreign criminal organizations.

Finally, there is no evidence that importation under the proposed SIP will result in a significant reduction in the cost of covered prescription drugs to affected consumers. For example, both FDA's proposal and RB 5366 exclude the most expensive medications in the U.S., including insulin, cell therapies, immunotherapies, and infused cancer drugs. In addition, only drugs approved in both the U.S. and Canada *under identical conditions* are eligible for importation, which will allow brand name sponsors to make minor changes to their most expensive drugs to avoid the risk of importation. For these and other reasons, RB 5366 is likely to apply only to an extremely small subset of the *least* expensive drugs available in Canada. As such, savings to Connecticut consumers from a legalized importation scheme are likely to be small.

For all these reasons, AAM respectfully opposes RB 5366 in its current form. AAM welcomes the opportunity to more fully discuss RB 5366 and its concerns with the Committee.

Sincerely,

Ashlie Van Meter

Senior Director, State Affairs

Cc: [redacted]